The Honorable Tana Lin

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

SUSAN FITZL and SAMANTHA HORTON, on behalf of themselves and a class of all others similarly situated,

Plaintiffs,

v.

AMAZON.COM, INC.,

Defendant.

No. 2:22-cv-00544-TL

DEFENDANT AMAZON.COM, INC.'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT

NOTE ON MOTION CALENDAR: SEPTEMBER 30, 2022

ORAL ARGUMENT REQUESTED

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Defendant Amazon.com, Inc. ("Amazon") moves to dismiss Plaintiffs' Complaint with prejudice pursuant to Fed. R. Civ. P. 8(a), 9(b), and 12(b)(6).

I. PRELIMINARY STATEMENT

Plaintiffs' Complaint challenges the labeling of certain over-the-counter ("OTC") cold and flu medicines containing dextromethorphan hydrobromide ("DXM"), a cough suppressant known as an antitussive. Plaintiffs allege that they purchased OTC medications containing DXM from Amazon for severe cold and flu symptoms, "took the medicine as directed," and "became unexpectedly drowsy." Compl. (Dkt. #1) ¶¶ 8, 9. Plaintiffs fail to state a claim for relief for several independent reasons.

First, federal law preempts Plaintiffs' claims. The federal Food and Drug Administration ("FDA") strictly regulates the labeling of OTC medicines through a "monograph" process. Over the course of 15 years, the FDA reviewed the efficacy and safety of antitussives, including DXM, and found "no data demonstrating that the antitussive ingredient[] … [DXM] … requires a drowsiness warning." 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). Accordingly, the FDA's final regulation concerning the labeling parameters for OTC medicines does not require products with DXM to display a drowsiness warning or disclose drowsiness as a side effect. Nor does it prohibit labeling OTC products containing DXM as non-drowsy or for daytime use. *See* 21 C.F.R. § 341.74 (titled "Labeling of antitussive drug products"). To protect the integrity of this regulatory framework, the federal Food, Drug, and Cosmetic Act ("FDCA") preempts (*i.e.*, prohibits) any state law claims that purport to impose requirements "different from," "in addition to," or "otherwise not identical with" the FDA's final labeling requirements for OTC medicines. 21 U.S.C. § 379r(a). Specifically, "§ 379r(a) preempts state law claims [1] that require additional information or labeling or [2] that prohibit labeling beyond what is expressly stated in the applicable federal requirements." *McFall v. Perrigo Co.*, No. 2:20-cv-07752-FLA, 2021 WL 2327936, at *8 (C.D. Cal. April 15, 2021) (citing cases).

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Nonetheless, Plaintiffs assert six state law claims that directly challenge the labeling of DXM-containing OTC medicines, alleging that the terms "non-drowsy" or "daytime" are false and misleading. *See* Compl. ¶¶ 31–34. Plaintiffs contend that Amazon should have instead disclosed drowsiness as a side effect, omitted the "non-drowsy" description, or changed the label to "less drowsy." *Id.* ¶¶ 31–36. Plaintiffs ignore, however, that "[w]ith respect to the labeling of OTC drugs, the whole point of section 397r is that it is not up to private litigants—or judges—to decide what is 'false or misleading.' It is up to the FDA." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 377 (S.D.N.Y. 2014). And "[b]ecause the FDA alone can balance the potentially competing concerns of safety and effectiveness, common law and state law liability that is also premised on a product's safety and effectiveness can only upset that balance." *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008). Section 379r therefore squarely preempts all of Plaintiffs' claims because, "[i]f successful, this litigation would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation." *Bowling*, 65 F. Supp. 3d at 376.

Second, the Complaint's conclusory allegations that DXM may cause drowsiness and that the challenged medicines caused Plaintiffs to feel "unexpectedly drowsy" do not state plausible claims for relief. Plaintiffs allege that they purchased and took the medicines targeting "severe" cold and flu symptoms. But they do not plead facts to establish that the medications caused their alleged drowsiness. For good reason: cold and flu viruses, among many other things, cause fatigue. "[W]ithout some further factual enhancement," the Complaint's speculation that the medicines caused Plaintiffs' drowsiness "stops short of the line between possibility and plausibility of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007).

Third, Plaintiffs' independent claims each suffer from additional deficiencies that warrant dismissal, including that: (1) Plaintiffs' statutory claims under Wisconsin and Ohio state law (Counts II and III) fail because Washington law governs all disputes between Plaintiffs and

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Amazon; (2) Plaintiffs' breach of express warranty claim (Count I) is barred by an explicit disclaimer of all warranties and Plaintiffs' failure to provide timely notice of their claim; (3) Plaintiffs' unjust enrichment claim (Count IV) and other requests for equitable relief fail because Plaintiffs have an adequate remedy at law for their alleged economic injuries; and (4) Plaintiffs' negligent and intentional misrepresentation claims (Counts V and VI) fall short of both the Rule 8(a) pleading standard and the Rule 9(b) particularity requirement.

For each of the above reasons, as detailed below, the Court should dismiss Plaintiffs' claims with prejudice.

II. BACKGROUND

A. Federal Regulation of Over-the-Counter Drugs

The FDA regulates most OTC medications through a monograph process. A monograph is a set of regulations that describes the conditions under which a category of drugs may be marketed without a prescription. *See* 21 C.F.R. § 330.1 (titled "General conditions for general recognition as safe, effective and not misbranded") and § 330.10 (titled "Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs"); *see also Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013) (describing the monograph process). A monograph is "like a recipe" for each category of OTC drugs: it "sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs" and specifies acceptable doses, formulations, and labeling for those drugs. *NRDC*, 710 F.3d at 75. An OTC drug that complies with its monograph "is generally recognized as safe and effective and is not misbranded." 21 C.F.R. § 330.1.

The FDA's monograph process is rigorous. A monograph is developed only after the FDA has appointed an advisory panel of independent experts, which "review[s] all available data" and reports its "conclusions and recommendations" to the FDA "with respect to the safety and effectiveness of the drugs." *Id.* § 330.10(a). Based on the panel's recommendations, the FDA publishes a proposed monograph for public comment, and then proceeds to publish a "tentative

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final monograph" ("TFM") for further public comment. *Id.* § 310.10(a)(7). "After reviewing [any] objections, the entire administrative record including all new data and information and comments, and considering the arguments made at any oral hearing," the FDA publishes a final monograph "establishing conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded." *Id.* § 310.10(a)(9).

B. Federal Labeling Requirements for Medicines Containing DXM

The FDA began the monograph process for OTC cold and cough medications in 1972. *See* 41 Fed. Reg. 38,312, 38,314 (Sept. 9, 1976). After an agency-appointed panel of experts studied the safety and efficacy of the medications, and following multiple rounds of public comment, the FDA published a TFM for OTC antitussives in 1983 (48 Fed. Reg. 48,576 (Oct. 19, 1983)) and a final monograph in 1987 (52 Fed. Reg. 30,042, 30,055–56 (Aug. 12, 1987) (codified at 21 C.F.R. § 341.74)). *See Carter*, 582 F. Supp. 2d at 1275–76 (C.D. Cal. 2008) (describing the OTC antitussive monograph process).

The final monograph that emerged from this 15-year process has comprehensive labeling requirements for products containing DXM. Specifically, the monograph regulates the indication statements, required warnings, and dosage directions that must appear on the label. *See* 21 C.F.R. § 341.74 (b)(3)(vi)–(vii), (c)(4)(v)–(vi), (d)(1)(iii) (titled "Labeling of antitussive drugs"). Importantly, the monograph neither requires a warning that drowsiness is a side effect of DXM, nor prohibits the labeling of a product containing DXM as "non-drowsy." The FDA arrived at this final monograph—with no restrictions like those Plaintiffs demand here—after affirmatively considering the relationship between DXM and drowsiness and documenting in the TFM that it was "*not aware of data demonstrating that* the antitussive ingredient[] … [DXM] … *require[s] a drowsiness warning*." 48 Fed. Reg. at 48,589 (emphasis added).

By contrast, the FDA requires that other OTC cough medications expressly warn of potential drowsiness. These warnings take two forms—that a medication "may cause drowsiness" or that it "may cause marked drowsiness." 21 C.F.R. §§ 341.72(c)(3) (requiring "drowsiness"

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warning for several antihistamines); 341.72(c)(4) (requiring "marked drowsiness" warning for products containing diphenhydramine or doxylamine); 341.85(c)(4) (requiring "marked drowsiness" warning when an antihistamine is combined with an oral antitussive). Tellingly, the FDA did not require any such drowsiness disclosure for products containing DXM. *Id.* § 341.74(c)(4)(i)–(vi) (listing warnings actually required for certain antitussives).

C. Plaintiffs' Allegations

Plaintiffs purchased medicines for "severe" cold and flu symptoms: Ms. Fitzl alleges she purchased a "Basic Care Vapor Ice Daytime and Nighttime ***Severe*** Cold and Flu combo pack," and Ms. Horton alleges she purchased a "Basic Care Daytime ***Severe*** and Nighttime ***Severe*** Cold and Flu combo pack." Compl. ¶¶ 8, 9 (emphasis added). Both "took the medication as directed" and, at some point thereafter, "became unexpectedly drowsy." *Id.*

Conspicuously absent from the Complaint is any allegation that the medicines actually caused either Plaintiff's alleged drowsiness. Plaintiffs' purchase of medicines for "severe" cold and flu symptoms indicates that both sought relief from cold and/or flu symptoms. The Complaint alleges no facts from which the Court can reasonably infer that the medicines, rather than Plaintiffs' preexisting sicknesses or one of the many other reasons one becomes tired, caused their alleged drowsiness. In fact, Plaintiffs offer no detail about their particular circumstances, resting their contention that DXM caused their drowsiness on speculation and assumption.

Plaintiffs instead allege that the medicines they took contain DXM, that documents found on the internet suggest to them that drowsiness can be a side effect of DXM, and that the medicine labels do not warn of the risk of drowsiness. At the same time, however, Plaintiffs concede that the FDA regulations "do not require products with [DXM] to include an affirmative 'drowsiness' warning." *Id.* ¶ 34. Nevertheless, Plaintiffs allege that the absence of a drowsiness warning "deprived [them] of the benefit of their bargain." *Id.* ¶¶ 6, 8–9, 37. Plaintiffs assert only economic harm, measured by either the amount they paid for the medicines or an unspecified amount they claim they would have somehow saved had the labeling been different. *Id.* ¶ 41.

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Based on these allegations, Plaintiffs assert claims for: (1) breach of express warranty; (2) violation of the Wisconsin Deceptive Trade Practices Act, Wis. Stat. Ann. §§ 100.18, *et seq.*, (as to Ms. Fitzl); (3) violation of the Ohio Deceptive Trade Practices Act, Ohio Rev. Code Ann. §§ 4165.01, *et seq.*, (as to Ms. Horton); (4) unjust enrichment; (5) negligent misrepresentation; and (6) intentional misrepresentation. Plaintiffs seek money damages, equitable relief (*i.e.*, restitution), and a vague, undefined injunction. *See* Compl. at p. 19 ("Prayer for Relief").

III. LEGAL STANDARD

"[T]o satisfy Rule 8(a)(2) a complaint must contain sufficient factual content 'to state a claim to relief that is plausible on its face.'" *Landers v. Quality Commc'ns, Inc.*, 771 F.3d 638, 641 (9th Cir. 2015) (quoting *Twombly*, 550 U.S. at 570). Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). Plaintiffs must allege *facts*—not mere "labels and conclusions[,]" "formulaic recitation[s] of the elements of a cause of action[,]" or "naked assertion[s] devoid of further factual enhancement"—to elevate their claims from merely possible, to plausible. *Id.* (internal quotation marks omitted).

Courts do not apply this analysis in a vacuum. Instead, "determining whether a complaint states a plausible claim is context specific, requiring the reviewing court to draw on its experience and common sense." *Iqbal*, 556 U.S. at 663–64; *see Grigsby v. Valve Corp.*, No. C12-0553JLR, 2012 WL 5993755, at *4 (W.D. Wash. Nov. 14, 2012) (recognizing that "context matters" and granting Rule 12(b)(6) motion). Further, "a complex, large-scale case such as a class action should naturally have a higher plausibility threshold than a simpler case." *Id.* Plaintiffs must also satisfy Rule 9(b)'s heightened pleading standard and plead their claims—all of which sound in fraud—with particularity. *See Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103–04 (9th Cir. 2003) (claims "grounded in fraud" must satisfy Rule 9(b), even if fraud is not a necessary element).

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IV. ARGUMENT

A. The FDCA Preempts Plaintiffs' Claims

1. The FDCA broadly preempts state law claims challenging the labeling of OTC antitussives

Congress enacted Section 379r of the FDCA to bring national uniformity to the labeling of OTC drugs. *See* 21 U.S.C. § 379r (titled "National uniformity for nonprescription drugs"). Section 379r thus contains an express preemption clause, prohibiting states from establishing "any requirement … that is different from or in addition to, or that is otherwise not identical with" federal law. *Id.* § 379r(a). This preemption is sweeping and reaches, among other things, any cause of action brought under state common law that purports to impose a labeling requirement that is different from, in addition to, or not identical with federal law on the subject. *See Reigel v. Medtronic, Inc.*, 552 U.S. 312, 324–25 (2008) (interpreting a similar preemption provision and finding that "reference to a State's 'requirements' includes its common-law duties"); *Carter*, 582 F. Supp. 2d at 1282 (explaining that *Reigel* and § 379r "suggest that virtually any state requirement that relates to the regulation of nonprescription drugs can be preempted, regardless of the common law theory under which it is brought").

"In the context of OTC drugs," courts have found FDCA preemption applies ***both*** "when a state law prohibits labeling that is permitted under federal law" ***and*** "when a state law prohibits labeling that is *not prohibited* under federal law[.]" *Wiltz v. Chattem, Inc.*, No. CV 15-1352-R, 2015 WL 3862368, at *1 (C.D. Cal. May 8, 2015); *see also Bowling*, 65 F. Supp. 3d at 375 ("The standard … is not whether a state law actively undermines federal law. It is whether the state law diverges from federal law *at all*."). Put another way, "§ 379r(a) preempts state law claims that require additional information or labeling or that prohibits labeling beyond what is expressly stated in the applicable federal requirements." *McFall*, 2021 WL 2327936, at *8; *see also Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 795 (2002) ("[W]hen a state law claim, however

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couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted.").

Final FDA monographs have preemptive effect under the FDCA. *See Youngblood v. CVS Pharmacy*, No. 2:20-cv-06251-MCS-MRW, 2021 WL 3700256, at *2–3 (C.D. Cal. Aug. 17, 2021) (mislabeling claims preempted by requirements in FDA monograph); *Kanter*, 99 Cal. App. 4th at 795 (discussing the preemptive effects of monographs). Preemption is especially appropriate in the monograph context because, "[w]ith respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to private litigants—or judges—to decide what is 'false or misleading.' It is up to the FDA." *Bowling*, 65 F. Supp. 3d at 377. Accordingly, where a final monograph regulates the labeling of an OTC drug, the FDCA precludes any state requirements, through common law claims or otherwise, "unless they are *identical* to federal standards." *Id.* at 375 (internal quotation marks omitted); *see also id.* at 377 (to defeat preemption "plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the label"); *McFall*, 2021 WL 2327936, at *8 (preemption operates if "the packaging elements Plaintiffs have identified as false or misleading … are required, or not prohibited under the statutes, regulations, and monographs that apply to OTC … products.").

2. Plaintiffs' state law claims targeting DXM labeling are preempted

Plaintiffs' claims concerning the labeling for OTC medicines containing DXM are preempted because "[i]f successful, this litigation would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation." *Bowling*, 65 F. Supp. 3d at 376. Plaintiffs allege that Amazon has engaged in false and misleading marketing because, according to them, "drowsiness is a documented side effect" of DXM that requires an express warning and gives rise to an implicit prohibition on labels bearing the terms "non-drowsy" and "daytime." Compl. ¶¶ 5, 14–32. Plaintiffs seek both to ***change*** the "non-drowsy" and "daytime" wording on the products' labeling (thus grafting a different, additional, and non-identical prohibition into the

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governing regulations) and to ***add*** a drowsiness warning (thus overturning the FDA's decision not to require such warnings). *See id.*, *see also id.* ¶ 37 (alleging that "[t]he product labels do not warn consumers that the products cause drowsiness, may cause drowsiness, or you may get drowsy from usage of such products").

Section 379r preempts exactly these types of proposed changes and additions to labeling requirements set forth in FDA monographs. *See*, *e.g.*, *Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 833 (N.D. Ill. 2021) (plaintiff's "claims are preempted because she seeks to impose additional obligations on [defendant] not imposed by the [monograph]"); *Youngblood*, 2021 WL 3700256, at *3 (dismissing claims "seeking additional, gratuitous representations" as "not compatible with the FDCA"); *Wiltz*, 2015 WL 3862368, at *2 (same); *Gisvold v. Merck & Co., Inc.*, 62 F. Supp. 3d 1198, 1203 (S.D. Cal. 2014) ("Because the proposed disclaimer plainly adds to and is not identical with the FDA's requirements, Plaintiff's action is expressly pre-empted"); *Kanter*, 99 Cal. App. 4th, at 797 ("Because all of plaintiffs' state law causes of action … are also based ultimately on the assertion that the labels on those products are no longer accurate or adequate, they … cannot escape preemption.").

Plaintiffs are likely to argue that their claims are not preempted because the FDA's antitussive monograph does not expressly *endorse* use of the term "non-drowsy" on labels for OTC products containing DXM. This argument is a nonstarter. As a practical matter, the FDA cannot list out every word that *is* permissible for every label for every type of OTC product. That is precisely why the FDCA prohibits not only state law claims that purport to impose requirements "different from" the FDA's labeling requirements, but also any claims that seek to impose requirements or restrictions "in addition to" or "otherwise not identical with" those labeling requirements. 21 U.S.C. § 379r(a).

But, more importantly, courts have rejected this argument, holding that state law cannot prohibit "labeling that is *not prohibited* under federal law." *Wiltz*, 2015 WL 3862368, at *1; *see also McFall*, 2021 WL 2327936, at *8 (same). This holds particularly true where, as here, the

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FDA specifically considered whether DXM causes drowsiness and declined to: (i) require the types of warnings Plaintiffs seek; or (ii) restrict the types of language, *i.e.*, "non-drowsy" or "daytime," that Plaintiffs challenge. Various cases offer instructive insight.

In *Carter v. Novartis*, the Central District of California dismissed state law claims challenging the labeling on certain OTC cough and cold medicines as safe for children under six. 582 F. Supp. 2d at 1276–77, 1284–85. During the monograph process for the medicines at issue, and after considering relevant evidence, the FDA only prohibited the use of the medicines to treat children under two. *Id.* at 1276–77. Citing "various studies, articles from the New York Times, and two recent clinical studies," the plaintiffs nonetheless brought fraud and warranty claims alleging that the defendants "knew or should have known" the products were dangerous to other children and should not have marketed them as "safe and effective for children under six." *Id.* The court found plaintiffs' claims preempted because the marketing statements were "based entirely upon FDA-approved labeling and advertising," which "explain[ed] the conditions under which the FDA … determined that OTC cough and cold medicine will be safe and effective." *Id.* at 1284–85. That was so because, while the FDA considered potential restrictions related to children under six, it ultimately did not prohibit labels from saying they were "safe and effective for children under six." *Id.*

The California Court of Appeals reached a similar conclusion in *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 456–57 (2015). In that case, the court held that a plaintiff could not pursue claims that it was misleading to label sunscreen as "sunblock," "waterproof," or "sweatproof," when the FDA had considered the issue but had not prohibited the use of those terms. *Id.*

Additionally, in *Bowling v. Johnson & Johnson*, the Southern District of New York rejected the plaintiffs' attempt to force the maker of Listerine to remove the statement "restores enamel" from its mouthwashes. 65 F. Supp. 3d at 373. There, the plaintiffs claimed the statement was false because, they alleged, enamel loss was permanent and no mouthwash could restore it.

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Id. The court found the claims preempted, however, because the FDA had issued regulations concerning appropriate labeling for mouthwash and did not prohibit use of the language "restores enamel." *Id.* at 376. The court reasoned that "[t]his case might be different if the FDA had issued no guidance as to dental hygiene products," but that, "[a]s it stands, … the FDA has issued a monograph directly on point but declined, in spite of that, to indicate … that 'Restores Enamel' is misleading." *Id.*; *see also Wiltz*, 2015 WL 3862368, at *2 (same).

Finally, in *McFall v. Perrigo Co.*, the Central District of California reiterated the broad preemptive scope of § 379r(a), which not only preempts claims that "require additional information or labeling" (*i.e.*, like adding a drowsiness warning), but also claims that "prohibit[] labeling beyond what is expressly stated in the applicable federal regulation" (*i.e.*, like prohibiting the terms "non-drowsy" or "daytime"). 2021 WL 2327936, at *8 (claims preempted if the challenged labeling is "not prohibited under [applicable] statutes, regulations, and monographs"). Although the *McFall* court found the claims at issue there not preempted, it did so because the TFM required the use of the term "children" and appeared to prohibit the use of the term "infant" (which was used on the challenged labels). *Id.* at *9–10.

Importantly, the above-described cases each turned on state law claims—like those asserted here—that sought to impose labeling requirements and restrictions on subject matters that the FDA had previously considered and regulated. That sets those cases, and this case, starkly apart from cases like *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753 (9th Cir. 2015), and its progeny, which turned instead on labeling challenges concerning subject matters *never* considered by the FDA and *not* addressed by any applicable federal regulations. *Compare Astiana*, 783 F.3d at 758–59 (holding that claims targeting the labeling of cosmetics as "natural" were not preempted because "the FDA ha[d] never issued regulations regarding the use of 'natural' on cosmetics labels"), *with Durnford v. MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018) (distinguishing *Astiana* because "[n]o statute or regulation governed the use of 'natural' on cosmetics labels" (internal quotation marks omitted)). In other words, *Astiana* stands for the unremarkable—and

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inapposite—proposition that preemption does *not* apply when "the FDA says nothing about the subject matter" of a plaintiff's claims. *Bimont v. Unilever U.S., Inc*., No. 14-CV-7749 (JPO), 2015 WL 5256988, at *3-5 (S.D.N.Y. Sept. 9, 2015) (interpreting *Astiana*).

Unfortunately, litigants and courts alike have misread and misapplied *Astiana*. The Central District of California in *Lemus v. Rite Aid Corp.*, for example, recently rejected preemption of "non-drowsy" labeling claims on the mistaken ground that *Astiana* held that preemption could only apply if the FDA had expressly authorized use of the term "non-drowsy" in its final regulations. *See* No. 22-cv-00253, 2022 WL 2721385, at *2-3 (C.D. Cal. July 7, 2022). Respectfully, the *Lemus* court's treatment of *Astiana* is incorrect. *Lemus* conspicuously fails to acknowledge, or analyze, that the FDA expressly considered the connection, if any, between DXM and drowsiness and the labeling parameters for medicines containing DXM. In other words, *Lemus* mistakenly ignores that the state law "non-drowsy" labeling claims in that case fall into the "considered and addressed" category like those in *Carter*, *Eckler*, and *Bowling*—which are preempted—and not into the "never been addressed" category of claims like those in *Astiana*.

Ultimately, the FDA has set forth specific requirements for the labeling of OTC medicines containing DXM. Through their claims, Plaintiffs seek to impose additional labeling requirements and graft additional, different, and non-identical prohibitions on top of those promulgated by the FDA. As such, "[i]f Plaintiffs were permitted to move forward with their claims, they would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder [which] … is exactly what the FDCA does not permit." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 36 (2d Cir. 2020); *see also Turek v. General Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added … are not identical to the labeling requirements imposed on such products by federal law, and so they are barred."); *Carter*, 582 F. Supp. 2d at 1285 (claims preempted where they would "impose liability upon Defendants for complying with FDA regulations"). Plaintiffs' claims are preempted and, therefore, the Court should dismiss the Complaint in its entirety and with prejudice.

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B. Plaintiffs Do Not Plausibly Allege that the Labels are False or Misleading

Plaintiffs' claims turn on the conclusory allegation that DXM causes or may cause drowsiness. *See* Compl. ¶¶ 23–41. From there, Plaintiffs contend that the labeling is false, deceptive, and misleading because it uses the terms "non-drowsy" and "daytime" and "do[e]s not disclose anywhere on the packaging that [the medicines] do or can cause drowsiness, or that drowsiness is a side effect." *Id.* ¶¶ 31–32. These allegations are insufficient under Rules 8(a) and 9(b) to sustain a plausible claim that the medicines cause or may cause drowsiness.

1. Plaintiffs fail to plausibly allege that DXM causes drowsiness

To support the contention that DXM causes drowsiness, Plaintiffs primarily rely on certain materials found on the internet. Those sources, however, do not support a plausible inference that drowsiness is, in fact, a "well-documented side effect" of DXM. *See* Compl. ¶ 24.

First, Plaintiffs misleadingly cite two papers for the proposition that "sedation is a well-known adverse event of [DXM]." *Id.* ¶ 29. In one, the very first paragraph belies Plaintiffs' allegation, stating that, as an antitussive, "DXM has strong safety and efficacy profiles *with no sedative* or addictive properties *at the recommended doses*." A. Siu & R. Drachtman, *Dextromethorphan: A Review of N-methyl-d-aspartate Receptor Antagonist in the Management of Pain*, 13 CNS Drug Reviews 1, pp. 96–106, 96 (2007) (emphasis added) (Ex. A to the Declaration of Ruby Nagamine ("Nagamine Decl.")).[1] It is only where the study addresses "overdoses" of DXM or its use "at higher doses" that it notes adverse effects that may include drowsiness. *Id.* at pp. 99, 102. The other study is equally unhelpful to Plaintiffs' Complaint, as it acknowledges that "a sedative effect … was … little reported" when DXM was used to treat pain, and that the pain relieving "effect of [DXM] is *not accompanied by a sedative effect*." E. Martin, *et al.*, *Dextromethorphan Analgesia in a Human Experimental Model of Hyperalgesia*, 131

[1] In deciding this Motion, the Court may consider each of the studies, papers, websites, and other materials expressly referenced or cited in the Complaint. *See Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007) ("[A] court may consider a writing referenced in a complaint but not explicitly incorporated therein if the complaint relies on the document and its authenticity is unquestioned.").

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Anesthesiology 2, pp. 365–66 (Aug. 2019) (emphasis added) (Ex. B to Nagamine Decl.). Both papers address the potential use of DXM to relieve pain at dosages higher than those recommended for antitussive purposes, and neither purports to establish a causal relationship between recommended dosages of DXM and drowsiness. *See Manuel v. Pepsi-Cola Co.*, 763 F. App'x 108, 109 (2d Cir. 2019) (finding no plausible inference that the term "diet" was false, inaccurate, or misleading where "[n]one of the studies purport to establish a causal relationship between non-nutritive sweeteners and weight gain to a degree that is sufficiently strong").

Second, Plaintiffs mischaracterize two online FAQ pages, which describe drowsiness as a potential symptom of an *overdose* of DXM. *See* Mayo Clinic, *Drugs and Supplements: Dextromethorphan (Oral Route)*, pp. 7–8 (listing "drowsiness" as a "[s]ymptom[] of overdose" and "drowsiness (mild)" as "[l]ess common or rare") (Ex. C to Nagamine Decl.); Nat'l Institutes of Health/Nat'l Library of Med., *Dextromethorphan: Medline Plus Drug Information*, p. 4 (listing "drowsiness" as a potential "[s]ympton[] of overdose") (Ex. D to Nagamine Decl.). Potential overdose symptoms have no bearing on Plaintiffs' allegation that proper use of the medicines at the recommended dosage cause drowsiness. While the National Institutes of Health webpage could potentially be read to suggest that drowsiness might be a side effect outside of the overdose context, the page provides no explanation, data, or support for that suggestion and thus lacks sufficient detail to "cross the threshold from allegations of correlation to causation." *Becerra v. Dr Pepper/Seven UP, Inc.*, No. 17-cv-05921-WHO, 2018 WL 3995832, at *6, *8–9 (N.D. Cal. Aug. 21, 2018) (finding studies cited by plaintiff did not "supply the plausibility of a causal link between Diet Dr Pepper and weight gain"), *aff'd*, 945 F.3d 1225 (9th Cir. 2019).

Third, Plaintiffs point to two documents, identified as "safety data sheets," from other entities, both of which are irrelevant to the medicines in this case. *See* Compl. ¶¶ 27–28. One document addresses a Robitussin product and the other concerns a commercially available, raw form of DXM. Pfizer, *Safety Data Sheet for Robitussin Cough and Chest Congestion DM*, dated Feb. 23, 2018, at p. 6 (emphasis added) (Ex. E to Nagamine Decl.); Santa Cruz Biotechnology,

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Inc., *Dextromethorphan Hydrobromide: Material Safety Data Sheet* (Ex. F to Nagamine Decl.). Neither document concerns the medicines at issue here. *See Becerra v. Dr Pepper/Seven Up, Inc.*, 945 F.3d 1225, 1230 (9th Cir. 2019) (affirming dismissal of claims where cited advertisements were "irrelevant to [plaintiff's] claims").

Finally, Plaintiffs take certain Federal Aviation Administration ("FAA") guidelines out of context, suggesting they show that DXM-containing medications cause drowsiness. The FAA guidelines, however, appear primarily focused on antihistamines or combination products containing antihistamines. They state that "[m]ost cough medications are safe for flight," but caution pilots to avoid "combination products with sedating antihistamines." FAA, *What Over-the-Counter (OTC) medications can I take and still be safe to fly?*, p. 3 (Nov. 13, 2019) (Ex. G to Nagamine Decl.). That guidance comports with FDA rules stating that products containing a combination of antitussives and antihistamines must disclose that they "may cause marked drowsiness." 21 C.F.R. § 341.85(c)(4). But DXM is not an antihistamine, and none of the medicines Plaintiffs challenge contain antihistamines.

2. Plaintiffs fail to allege that the medicines as a whole cause drowsiness

Plaintiffs also fail to plausibly allege that the challenged medicines as a whole—which combine DXM with other active ingredients—cause drowsiness. This is important because courts have rejected attempts to work around the pleading requirements by focusing on one ingredient and ignoring the product as a whole. *See In re GNC Corp.*, 789 F.3d 505, 510–11, 516 (4th Cir. 2015) (dismissing deceptive marketing claims because "Plaintiffs failed to allege that *all* of the purportedly active ingredients in each product are ineffective" and thus did not "adequately plead falsity of the representations regarding the products as a whole."); *Toback v. GNC Holdings, Inc.*, No. 13-80526-CIV, 2013 WL 5206103, at *5 (S.D. Fla. 2013) (allegations regarding the inefficacy of two ingredients do not plausibly suggest that the product "*as a whole* does not function as advertised" (emphasis added)); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-cv-727-LAB-MDD, 2012 WL 5382218, at *6 (S.D. Cal. Nov. 1, 2012) (dismissing false advertising claim where "none of

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these studies actually involved Equate" and "it is the overall formulation that's behind the representation").

Without any plausible and specific allegations that DXM alone—or any of the medicines as a whole—cause drowsiness, the Complaint fails to state a claim for relief and should be dismissed. *See Aloudi v. Intramedic Research Grp., LLC*, 729 F. App'x 514, 516 (9th Cir. 2017) (affirming dismissal where plaintiff's allegations did not involve scientific testing of the actual challenged product); *see also Excevarria v. Dr Pepper Snapple Grp., Inc.*, 764 F. App'x 108, 109–10 (2d Cir. 2019) (affirming dismissal where "[n]one of the studies cited" supported mislabeling claims); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 141 (E.D.N.Y. 2015) (dismissing deception claims because cited studies did not raise a plausible inference that the label was false).

2. Plaintiffs fail to plausibly allege that the medicines caused their alleged drowsiness

Plaintiffs also attempt to base their central allegation—that DXM causes drowsiness—on anecdotal evidence of their own personal experiences with one medicine. But, the Complaint offers no details or fact-based allegations about their experiences to support the assumption. The Complaint does not even allege that the medicines Plaintiffs took actually caused their drowsiness. Plaintiffs instead want the Court to assume that their drowsiness, coming sometime after they took the medicine (they do not say how long), must have been attributable to DXM, rather than to one of the many other possible causes for drowsiness (*e.g.*, large meals, pre-existing conditions, sickness, long hours, or a lack of sleep). This is insufficient.

As explained above, when determining whether the Complaint states a plausible claim, "context matters" and the Court must "draw on its experience and common sense." *Iqbal*, 556 U.S. at 663–64; *Grigsby*, 2012 WL 5993755, at *4. Here, Plaintiffs presumably purchased the medicines to treat cold and/or flu symptoms that they were experiencing at the time. Drawing on common sense, those symptoms could be, and likely were, a contributing factor to any drowsiness Plaintiffs may have experienced. Without concrete factual allegations plausibly tying Plaintiffs'

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drowsiness to the medicines, the Complaint stops short of the line between mere possibility and plausibility. *See*, *e.g.*, *Aloudi*, 729 F. App'x at 517 (rejecting anecdotal allegations that plaintiffs' failure to lose weight plausibly supported claims that weight-loss based marketing was false); *Toback*, 2013 WL 5206103, at *6 (rejecting plaintiff's allegations that joint health products "did not repair his cartilage" and thus "did not function as advertised").

C. Plaintiffs' Claims Each Fail for Separate and Independent Reasons

1. The Conditions of Use bar non-Washington law claims under Wis. Stat. Ann. § 100.18 and Ohio Rev. Code § 4165.01

By purchasing the products from Amazon.com (Compl. ¶¶ 8–9), Plaintiffs accepted and agreed to Amazon's Conditions of Use ("COUs").[2] *See* COUs, dated May 21, 2021, at p. 1 (providing that by using "Amazon products or services," an Amazon customer agrees to comply with the COUs).[3] Amazon's COUs form a valid and enforceable contract. *See Wiseley v. Amazon.com, Inc.*, 709 F. App'x 862, 863 (9th Cir. 2017) ("The [COUs] … created a valid contract between Amazon and its customers[.]"). The COUs unambiguously state that Washington law governs all disputes between Amazon and Plaintiffs:

> By using any Amazon Service, you agree that applicable federal law, and the laws of the state of Washington, without regard to principles of conflict of laws, will govern these Conditions of Use and any dispute of any sort that might arise between you and Amazon.

COUs at p. 4.

Federal courts sitting in diversity apply the choice-of-law rules of the forum state. *Bryant v. Wyeth*, 879 F. Supp. 2d 1214, 1220 (W.D. Wash. 2012). Under Washington law, courts

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[2] As the Court has explained, customers "accept the COU every time they make a purchase on Amazon.com; to make a purchase, customers must click a button next to text that says 'by placing your order, you agree to Amazon.com's *privacy notice* and *conditions of use*,' the [emphasized] portions also bearing hyperlinks to the eponymous documents." *Ekin v. Amazon Servs., LLC*, 84 F. Supp. 3d 1172, 1173 (W.D. Wash. 2014).

[3] *See* Exhibit H to Nagamine Decl. The COUs are integral to Plaintiffs' claims and Amazon's defenses, such that the court may consider them on a motion to dismiss. *See Garner v. Amazon.com, Inc.*, No. C21-0750RSL, 2022 WL 1443680, at *2–3 (W.D. Wash. May 6, 2022) (considering certain Amazon online terms and FAQs in connection with a motion to dismiss). The Court may also take judicial notice of the COUs. *See id.* at *3; *see also* Amazon's Request for Judicial Notice ("RJN"), at p. 1 (filed contemporaneously herewith).

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"generally enforce choice of law provisions," unless another state has "a materially greater interest than the chosen state" and application of the chosen state law would contravene "a fundamental policy" of the other state. *ACD Distrib., LLC v. Wizards of the Coast, LLC*, No. C18-1517JLR, 2020 WL 3266196, at *4 (W.D. Wash. June 17, 2020) (internal quotation marks omitted), *aff'd*, No. 20-235986, 2021 WL 4027805 (9th Cir. Sept. 3, 2021). Application of Washington law does not contravene public policy. *See id.* at *5–6; *see also Wiseley*, 709 F. App'x at 863 (enforcing Washington choice-of-law provision in Amazon's COUs because "applying Washington law is not contrary to a fundamental policy of California law"). Amazon's COUs therefore preclude Plaintiffs from stating claims under the Wisconsin and Ohio Deceptive Trade Practices Acts (Counts II and III). *See Chung v. Vistana Vacation Ownership, Inc.*, 719 F. App'x 698, 698 (9th Cir. 2018) (holding that where the parties' agreement selected the governing law, the district court properly dismissed claims under another state's statute); *ACD Distrib., LLC*, 2020 WL 3266196, at *6 (enforcing Washington choice-of-law provision and dismissing Wisconsin law claim).

2. Plaintiffs' breach of warranty claim fails for several reasons

Plaintiffs' breach of warranty claim (Count I) fails for three additional reasons.

First, Amazon unequivocally disclaimed all express and implied warranties for the products Plaintiffs purchased. The Amazon COUs provide in relevant part that:

> AMAZON MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AS TO THE OPERATION OF THE AMAZON SERVICES, OR THE INFORMATION, CONTENT, MATERIALS, PRODUCTS (INCLUDING SOFTWARE) OR OTHER SERVICES INCLUDED ON OR OTHERWISE MADE AVAILABLE TO YOU THROUGH THE AMAZON SERVICES, UNLESS OTHERWISE SPECIFIED IN WRITING. . . .
>
> TO THE FULL EXTENT PERMISSIBLE BY LAW, AMAZON DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

COUs at pp. 3–4. This waiver is consistent with Wash. Rev. Code § 62A.2-316, which expressly permits parties to disclaim or modify warranties. And while the Washington Supreme Court held in *Berg v. Stromm* that disclaimers in consumer automobile purchases must be explicitly negotiated

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and set forth with particularity, the court subsequently declined to extend those requirements to certain other transactions analogous to Plaintiffs' purchases here.

In *Travis v. Washington Horse Breeders Ass'n, Inc.*, the Washington Supreme Court expressed its "reluctan[ce] to extend the [*Berg*] rule in other circumstances" and declined to do so with respect to auctions, reasoning that auctions do not involve "negotiations such as are typically found in the purchase of an automobile" and the conditions of sale "were in large, bold type," "were legible and easy to read," and the "final bill of sale was on a single page, easy to read, and understandable." 111 Wash. 2d 396, 403 (1988). The court further noted that one purpose of an auction is "to avoid face-to-face negotiations" and thus serve as "a cost-saving device in which face-to-face negotiations, except as to price, are not engaged in by the parties." *Id.* at 403–04. Plaintiffs' purchases here exhibit many of the same qualities as the auction considered in *Travis*. As online purchases, Plaintiffs' transactions do not involve face-to-face negotiations. The Amazon COUs, moreover, set forth the express disclaimer in all capital letters, in a separate section entitled "DISCLAIMER OF WARRANTIES AND LIMITATION OF LIABILITY", and in clear, easy-to-read, and plainly understandable language. *See* COUs at pp. 3–4. The Court should apply *Travis* to enforce the disclaimer in Amazon's COUs and dismiss Plaintiffs' warranty claim.

Second, Plaintiffs have not sufficiently alleged damages. Courts generally measure damages for breach of warranty as "the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted …." Wash. Rev. Code § 62A.2-714(2). Although the Complaint states, in conclusory fashion, that Plaintiffs "overpaid" or paid a "price premium" for non-drowsy medicines, Plaintiffs offer no detail regarding the costs of the medicines they purchased or the value of the products they allegedly received. Nor do they allege that "non-drowsy" medicines actually cost more than similar cold and cough medications that are not labeled as "non-drowsy." Plaintiffs, therefore, have not plausibly alleged a price premium theory.

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Third, Plaintiffs failed to provide timely notice of their breach of warranty claim. Washington law requires a buyer, "within a reasonable time after he or she discovers or should have discovered any breach[,]" to "notify the seller of breach or be barred from any remedy." Wash. Rev. Code § 62A.2-607(3)(a). Here, Plaintiffs purchased the medicines in September 2021 (Ms. Horton) and January 2022 (Ms. Fitzl), but did not send notice to Amazon until April 13, 2022, and filed suit just six business days later. *See* Compl. ¶ 57. The purpose of the notice requirement is to provide a seller with a reasonable opportunity to take remedial action, such as repairing or replacing defective items, reducing damages, or negotiating settlements. *See Alvarez v. Chevron Corp.*, 656 F.3d 925, 932 (9th Cir. 2011) (purpose of identical California law is "to allow the breaching party to cure the breach and thereby avoid the necessity of litigating the matter in court"). Here, Plaintiffs failed to fulfill that requirement and did not afford Amazon a reasonable time to investigate and address Plaintiffs' claims before they filed suit. Washington law bars Plaintiffs' express warranty claim as a result of this failure. *See* Wash. Rev. Code § 62A.2-607(3)(a) (providing that insufficient notice bars remedies for alleged breach of warranty).

3. Plaintiffs fail to state an unjust enrichment claim, or other grounds for equitable relief, because they do not allege the lack of an adequate remedy at law

Plaintiffs seek equitable relief under their unjust enrichment claim (Count IV, requesting restitution and disgorgement) and Wisconsin and Ohio statutory claims (Counts II and III, unspecified relief). *See* Compl. ¶¶ 69 (Wisconsin law), 80 (Ohio law), 84–85 (unjust enrichment). Plaintiffs, however, cannot obtain equitable relief because they have not established, and cannot establish, that they lack an adequate remedy at law. *See Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020) (finding that plaintiff "must establish that she lacks an adequate remedy at law before securing equitable restitution"); *Clark v. Eddie Bauer LLC*, No. C20-1106-JCC, 2021 WL 1222521, at *4 (W.D. Wash. Apr. 1, 2021) ("Federal courts are precluded from awarding equitable relief when an adequate legal remedy exists" (internal alternations omitted)). At the pleading stage, "the complaint must *first* provide sufficient allegations to explain how a

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legal remedy … [is] inadequate." *Clark*, 2021 WL 1222521, at *4. To do so, plaintiffs must "allege some facts suggesting that damages are insufficient to make them whole." *Gibson v. Jaguar Land Rover N. Am., LLC*, No. CV 20-00769-CJC(GJSx), 2020 WL 5492990, at *4 (C.D. Cal. 2020). Claims based solely on economic injury are classic examples of claims with an adequate remedy at law—*i.e*, monetary damages—that preclude awards of equitable relief. *See Clark*, 2021 WL 1222521, at *4 (dismissing claims for equitable relief in false advertising case where plaintiff only alleged financial harm); *Sharma v. Volkswagen AG*, 524 F. Supp. 3d 891, 908 (N.D. Cal. Mar. 9, 2021) (alleged loss of money and loss in value of purchased vehicles are "exactly the type of injury for which legal remedies are appropriate").

While Plaintiffs request equitable relief, their Complaint lacks any explanation as to *why* potential monetary damages are inadequate or *why* Plaintiffs are otherwise entitled to such relief. *See* Compl. ¶¶ 69 (noting only that Ms. Fitzl seeks equitable relief under Wisconsin law), 80 (noting only that Ms. Horton seeks equitable relief under Ohio law), 84–85 (requesting restitution and disgorgement under unjust enrichment claim). Plaintiffs, in fact, cannot make this necessary showing, as their allegations of economic harm are quintessential injuries for which legal remedies are adequate. Indeed, Plaintiffs expressly seek money damages for their alleged harm. *See id.* ¶¶ 68, 79–80, 93, 103. Plaintiffs do not suggest how an award of restitution or other equitable relief would provide them any additional benefits. *See Hamm v. Mercedes-Benz USA, LLC*, No. 6:16-cv-03370-EJD, 2022 WL 913192, at *5 (C.D. Cal. Mar. 29, 2022).

Because Plaintiffs are not entitled to equitable relief, the Court should dismiss: (1) the unjust enrichment claim; (2) the Wisconsin and Ohio law claims to the extent they seek equitable relief; and (3) the request for "equitable relief, including restitution and disgorgement." *See Sonner*, 971 F.3d at 844 (affirming dismissal of "equitable restitution" claims); *Sharma*, 524 F. Supp. 3d at 907–09 (dismissing claims for unjust enrichment and restitution under California law); *Gibson*, 2020 WL 5492990, at *4 (dismissing state statutory claim seeking restitution).

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4. Plaintiffs do not allege plausible misrepresentation claims

Plaintiffs have also failed to plead either intentional or negligent misrepresentation. To assert a claim for intentional misrepresentation (Count VI), Plaintiffs must allege: (1) the existence of a representation of material fact that is false; (2) Amazon's knowledge of its falsity and intent that Plaintiffs act on it; (3) Plaintiffs' ignorance of the falsity of the representation; (4) Plaintiffs' reliance on the representation; and (5) damages suffered by Plaintiffs as a result. *See Frias v. Asset Foreclosures Servs., Inc.*, 957 F. Supp. 2d 1264, 1271 (W.D. Wash. 2013). To plead a claim for negligent misrepresentation (Count V), Plaintiffs must allege that: (1) Amazon supplied false information for the purpose of guiding others in business transactions; (2) Amazon knew or should have known that the information would guide Plaintiffs; (3) Amazon negligently obtained or communicated the false information; (4) Plaintiffs justifiably (*i.e.*, reasonably) relied on that information; and (5) the false information proximately caused Plaintiffs damage. *See Seattlehaunts, LLC v. Thomas Family Farm, LLC*, No. C19-1937 JLR, 2020 WL 5500373, at *7 (W.D. Wash. Sept. 11, 2020). Plaintiffs fail to plausibly plead any of the foregoing, let alone with the particularity required by Rule 9(b). *See Vess*, 317 F.3d at 1103; *Frias*, 957 F. Supp. 2d at 1271.

First, Plaintiffs fail to allege a false representation. They offer no factual basis upon which this Court may plausibly infer that the non-drowsy medicines cause drowsiness when taken as directed and at the recommended dosage. *See* Section IV.B, *supra.*

Second, Plaintiffs offer virtually no facts about their purchases and experiences with the medicines. Instead, they allege only conclusory statements and bare recitations of the elements of their claims, including their personal reliance on purported "representations and warranties" on the products' labels. *See* Compl. ¶¶ 8–9 (identical, conclusory allegations), 86–103 (rote recitation of elements). Plaintiffs similarly do not allege any plausible basis on which to infer causation—resting solely on the allegations that they became "unexpectedly drowsy" at some undisclosed time after they took the medication. *Id.* ¶¶ 8–9.

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Third, Plaintiffs plead no facts to suggest that Amazon had, or reasonably should have had, knowledge of the alleged falsity of the "non-drowsy" representation. Instead, Plaintiffs state, in conclusory fashion, that Amazon "knew or should have known" its representations were inaccurate because DXM "causes drowsiness." Compl. ¶¶ 38–40, 89–90, 96. Again, as discussed above, Plaintiffs have failed to make the threshold showing that DXM causes drowsiness. *See* Section IV.B, *supra*. But even if they had, the Complaint does not provide any allegations, fact-based or not, to plausibly infer that the drowsiness effect was so well-known and documented that Amazon actually knew or reasonably should have known that it was a potential side effect. To the contrary, the FDA monographs support the opposite conclusion—that is, the lack of data supporting a drowsiness warning for DXM. *See* 48 Fed. Reg. at 48,589

Finally, Plaintiffs fail to plausibly allege actionable damages. The Complaint asserts two theories of injury: (1) Plaintiffs paid a "price premium" for non-drowsy, daytime medicines; and (2) Plaintiffs "would not have purchased" them absent the alleged misrepresentation. *See* Compl. ¶¶ 37, 41, 56, 67, 93, 103. As to the alleged price premium, Plaintiffs' theory fails because they do not sufficiently allege any price premium. *See* Section IV.C.2. As to the second theory, Plaintiffs do not allege, or even suggest, that the medicines are worthless or that they did not obtain a benefit from taking them (*i.e.*, actual suppression of cough or relief of other cold- or flu-like symptoms). As such, Plaintiffs' allegations do not support claims to the full price of the medicine they purchased. *See Salter v. Heiser*, 39 Wash. 2d 826, 832 (1951) (holding that damages for misrepresentation claims are typically measured by the benefit of the bargain, "the difference between the value had the misrepresentation been true and the actual value").

V. CONCLUSION

For the foregoing reasons, Amazon respectfully requests that the Court: (1) grant Amazon's Motion to Dismiss; (2) dismiss all claims alleged in Plaintiffs' Complaint with prejudice and without leave to amend; and (3) grant any such other relief as the Court deems just and necessary.

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DATED July 15, 2022

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Certification of Conferral

Pursuant to the Court's Standing Order for All Civil Cases, Sections II.D. and II.I., the undersigned counsel for Defendant Amazon.com, Inc. certifies that, via a telephone call on July 7, 2022, counsel for Defendant conferred with counsel for Plaintiffs about the contents of the foregoing Motion to Dismiss.

DATED July 15, 2022

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